



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0041]

Availability of Compliance Guide for Residue Prevention and
Response to Comments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of the final revision of the compliance guide for the prevention of violative residues in livestock slaughter establishments. In addition, this notice summarizes and responds to comments received on the guide and residue testing issues that FSIS raised previously in the Federal Register.

ADDRESSES: A downloadable version of the revised compliance guide is available to view and print at http://www.fsis.usda.gov/PDF/Residue_Prevention_Comp_Guide.pdf.

No hard copies of the compliance guide have been published.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, at Telephone: (202) 205-0495, or by Fax: (202) 720-2025

SUPPLEMENTARY INFORMATION:

I. Background

On April 25, 2012, FSIS announced the availability of a compliance guide for residue prevention (77 FR 24671) and requested comment on the guide. FSIS explained that the guide emphasizes that establishments, especially those that slaughter dairy cows and bob veal calves, should apply five basic measures to reduce or prevent the occurrence of violative residues. The guide recommends that establishments should: (1) confirm producer history; (2) buy animals from producers who have a history of providing residue-free animals and have effective residue prevention programs; (3) ensure that animals are adequately identified to enable traceback; (4) supply information to FSIS at ante-mortem inspection showing that animals in the lot did not come from repeat violators; and (5) notify producers in writing if their animals are found to have violative residues. Similarly, the guidance recommends that establishments notify producers in writing if their animals are found to have residues that are detectable but that do not exceed the tolerance or action levels established by the Food and Drug Administration (FDA) and the Environmental Protection Agency.

FSIS also explained that the compliance guide discusses the

Agency's Residue Repeat Violator List. In addition, FSIS explained recent changes to the list, including that the list now includes only producers who have provided more than one animal with a violative residue during the past 12 months, and asked for comment on recent revisions to the list.

FSIS also announced that it recently increased testing for residues of carcasses in establishments with violations associated with the same producer or at establishments that fail to apply the residue control measures described in the compliance guide. Finally, FSIS also announced it intended to increase testing for residues in animals from producers who are under an injunction obtained by the FDA because of drug use practices that have led to residue violations.

In response to the comments it received, FSIS has updated the guidance document by substituting "residue free" and "drug free" with the phrase "free from violative residues." In addition, FSIS has included a discussion of means of livestock identification other than those discussed in the initial guidance that should be considered by livestock slaughter establishments when back tags are lost or prove ineffective in maintaining the identity of the animals.

The guide includes recommendations rather than regulatory requirements. FSIS encourages livestock slaughter

establishments to follow this final guide.

As for increased testing of animals from producers under an injunction obtained by FDA, FSIS and FDA continue to discuss how this testing can best be done. FSIS did not receive any comments on this issue. FSIS advises that it does intend to implement this increased testing.

FSIS also did not receive any comments on recent increases in testing of carcasses for residues.

II. Comments and Responses

FSIS received a total of 12 comment letters in response to the April 2012 notice from professional veterinary associations, national trade organizations, private citizens, and an animal welfare advocacy organization. Following is a summary of the comments and FSIS's responses.

Comment: Several comments stated that only a small percentage of livestock receiving a back tag at the livestock market or sale barn actually retain those tags all the way to slaughter. One comment estimated that 80 percent of back tags placed on swine fall off before the animals are presented for slaughter. Several comments conjectured that if processors refuse to purchase animals without identification as recommended by FSIS, owners of animals that unwittingly lose their back tags while in transit or holding pens will be denied market access.

As an alternative to back tags, two comments requested that FSIS mandate the use of permanent ear identification tags in swine.

Response: FSIS acknowledges that incidental loss of back tags does occur while livestock are in transport and holding areas. However, FSIS believes, in some cases, back tags prove to be an acceptable form of identification. If back tags do not work in certain situations, FSIS recommends that establishments use other means of identification, like producer ear tags, feedlot identification tags, tattoos, and calf-hood tags ("bangs"). FSIS has modified the guide to address animal identification options for establishments to consider when incidental loss of back tags occurs.

FSIS has limited authority to mandate the use of specific identification devices, permanent or otherwise, on livestock presented for slaughter. Therefore, FSIS does not intend to propose changes to its regulations to require specific identification devices at this time.

Comment: Several comments opposed FSIS's recommendation that slaughter establishments notify animal producers if their animals are found to have non-violative levels of a drug residue because the information will likely confuse producers.

Response: On November 28, 2000, FSIS informed establishments that if their HACCP plans included residue

controls that incorporate the best available preventive practices for slaughter establishments, if they implement those controls effectively, and if they supply FSIS with information about violators, then the Agency will not treat violative residue findings by the establishment that are followed by appropriate corrective actions as noncompliance (65 FR 70809). The Federal Register notice went on to recommend that slaughter establishments notify animal producers in writing of both violative and non-violative residue findings as one of several "best preventive practices." As reaffirmed in the compliance guide, FSIS believes that such an approach will result in a decrease in violative residue findings because evidence of non-violative residues is an indication of lack of care in drug use by that producer.

Comment: Several comments requested that FSIS resume publishing the Residue Violator List in addition to the revised Residue Repeat Violator List. According to the comments, information contained within the discontinued Residue Violator List was used by certain trade organizations to target outreach on residue avoidance to reduce the probability that a repeat violation would occur.

Response: In 2011, to avoid confusion, FSIS stopped publishing the monthly Residue Violator (Alert) List that

included the names of any producer, including first-time offenders, with a residue violation in the previous 12-months. FSIS replaced that list with the Residue Repeat Violator List. Published weekly, the Residue Repeat Violator List identifies producers who repeatedly (i.e., on more than one occasion) within a 12-month period have sold animals for slaughter whose carcasses were found by FSIS to contain a violative level of a chemical residue.

FSIS recognizes that posting the name of a livestock producer to a publicly-available list of residue violators may potentially result in significant economic harm to that producer. Moreover, the incentive of removal of the producer's name from the Residue Repeat Violator List, which motivates repeat violators to improve their operations to prevent violative residues, will be weakened if producers with only one violation are listed on the web site. Finally, FSIS notes that many first-time residue violators do not go on to become repeat violators within the designated 12-month period. Therefore, FSIS does not intend to resume publishing names of producers with a single violation within a 12-month period.

Comment: Because producers or suppliers can sell livestock to multiple Federal establishments, one comment suggested that FSIS consolidate residue test results from the supplier or

producer and set an acceptance level of non-violative samples that would trigger removal of a producer from the Residue Repeat Violator List rather than use a hard 12-month timeframe.

Response: FSIS would need to evaluate existing data to set a level of acceptable non-violative residue sample results that would trigger removal of a producer from the Residue Repeat Violator List. Given the time and resources that it would take to perform this evaluation, FSIS finds that the passage of time without a violation remains the appropriate criterion for removal from the list and is not making any changes to the Residue Repeat Violator list at this time.

Comment: Two comments requested that FSIS amend the compliance guide by substituting "residue-free" and "drug residue free" with the phrase "free from violative residues".

Response: FSIS agrees with the suggested changes and has modified the compliance guide accordingly.

Comment: Two comments expressed various concerns about drug residues in horses destined to be slaughtered for human consumption.

Response: In January 2010, the USDA Office of Inspector General determined in its review of the FSIS National Residue Program for Cattle that cull dairy cows and bob veal account for 90 percent of the residues found in animals presented for

slaughter. Therefore, the guide focuses primarily on establishments that slaughter these livestock. However, this guide will be useful to any establishments that slaughter horses under Federal inspection in the future. By following the recommendations in the guidance, horse slaughter establishments would employ practices that help them avoid receiving horses with residues.

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Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.

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directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: May 20, 2013

Alfred V. Almanza,
Administrator.

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